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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,259	10/17/2001	Bo Qiu	271/289	8229

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,259	QIU ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26March2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *2-13,17-28 and 31-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-16,29 and 30* is/are rejected.

7)☒ Claim(s) *29 and 30* is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 26March2002, paper#13, is acknowledged. Claims 1, 2, 3, 16, 17, 18, 31, 32, and 33 have been amended.

Applicant's election, with traverse, of Invention VII, claims 1, 14, 15, 16, 29, and 30, drawn to polypeptide GMTFRAQEGAFLTG-(beta-A)(beta-A)C, classified in class 424, subclass 190.1 is acknowledged. The traversal is on the grounds that the restriction is contrary to the Patent Office's own practice with respect to examination of multiple sequences in an application, M.P.E.P. §803.04. This is not found persuasive because M.P.E.P. §803.04, second paragraph, states" "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*"

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-45 are pending Claims 2-13, 17-28 and 31-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 1, 14, 15, 16, 29, and 30, drawn only to polypeptide GMTFRAQEGAFLTG-(beta-A)(beta-A)C are under consideration.

Specification

4. The disclosure is objected to because of the following informalities:

page 1) line 11, contains blank spaces which are application number and filing date,

page 2) line 7, 'anlayte' should be 'analyte',

page 3) line 32, 'and' should be 'an',

page 4) line 20, 'teat' should be 'test',

page 6, line 22, 'polymenrs' should be 'polymers'; line 30, what is 'guluronic',

page 8) line 17, 'ammo' should be 'amino',

page 10) line 24, delete 'of',

page 13) line 6, what is 'remove I bound',

page 20) line 10 what is 'taken as a. positive'; line 12, '1 .0' should be '1.0',

Appropriate correction is required.

5. M.P.E.P.§2422.03, paragraph 9 recites:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the"Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

Throughout the specification are numerous instances wherein sequences are listed without the required SEQ ID NO:.

6. The following is a recitation of 37 C.F.R. §1.74, Reference to Drawings:

> When there are drawings, there shall be a brief description of the several views of the drawings, and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals (preferably the latter).

The specification does not contain a section entitled, "Brief Description of Drawings".

Claims Objections

7. Claims 29 and 30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 29 depends from claim 28. Claim 28 is drawn to a vaccine comprising an epitope polypeptide with an amino acid sequence GMTFRAQEGAFLTG-(beta-A)(beta-A)C. The term "with" is closed claim language which restricts the sequence of the claimed epitope polypeptide to GMTFRAQEGAFLTG-(beta-A)(beta-A)C. Claim 29 broadens the scope of the claimed language in the that now the claimed epitope polypeptide "comprises" GMTFRAQEGAFLTG-(beta-A)(beta-A)C.

Claim 30 depends from claim 29. Claim 30 is drawn to an epitope polypeptide which "consists essentially of" GMTFRAQEGAFLTG-(beta-A)(beta-A)C. As with claim 29, this language broadens the scope of claim 28 in that the claimed epitope polypeptide may "comprise" GMTFRAQEGAFLTG-(beta-A)(beta-A)C so long as the structure does not materially alter the function of the polypeptide.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 16, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptide GMTFRAQEGAFLTG-(beta-A)(beta-A)C as one component of a composition which binds with antibodies of Lyme disease patients, does not reasonably provide enablement for vaccines comprising the polypeptide GMTFRAQEGAFLTG-(beta-A)(beta-A)C as one component. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - The instant claims are drawn to a vaccine composition comprising GMTFRAQEGAFLTG-(beta-A)(beta-A)C as one component.

The state of the prior art indicates that some polypeptides can be used as vaccine agents to protect individuals against Lyme disease. However, there is a lack of predictability in the art that any one peptide, synthetic or natural, will be protective without actually testing the peptide.

The amount of direction or guidance present in the instant specification is sufficient for making the claimed polypeptide and for using the polypeptide GMTFRAQEGAFLTG-(beta-A)(beta-A)C as one component of a composition which binds with antibodies of Lyme disease patients. However, there is a lack of examples or guidance for the scope of the instant claims, i.e., a vaccine composition comprising of GMTFRAQEGAFLTG-(beta-A)(beta-A)C.

Given the lack of predictability of success concerning polypeptides as vaccines against Lyme Disease, the quantity of experimentation necessary for determining whether the claimed composition can be utilized as a vaccine constitutes merely an invitation to experiment without a reasonable expectation of success.

11. Claims 14 and 15 recites the limitation "the composition of matter" in line 1. There is insufficient antecedent basis for this limitation in the claims as claim 1 from which both depend does not recite "composition of matter".

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 14, 15, 16, 29, and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1, 14, and 15 of copending Application No. 09/982,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims are not structurally different.

The claims of copending Application No. 09/982,264 are drawn to a "kit" comprising GMTFRAQEGAFLTG-(beta-A)(beta-A)C. The instant claims are drawn to a polypeptide or vaccine comprising/consisting of GMTFRAQEGAFLTG-(beta-A)(beta-A)C. The only component listed in both sets of claims are the polypeptide GMTFRAQEGAFLTG-(beta-A)(beta-A)C. Thus, while 09/982,264 recites a "kit" and the instant claims recite "composition", there is no difference in the recitation of components of the two sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

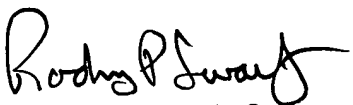
Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 22, 2003